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## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re the Patent Application of:<br><br>Applicant: GOLD, et al.<br><br>Serial No.: 09/927,121<br><br>Filed: August 10, 2001<br><br>Title: METHOD AND COMPOSITION FOR ALTERING A B CELL MEDIATED PATHOLOGY | Group Art Unit: 1644<br><br>Examiner: Jessica H. Roark<br><br>Certificate of Mailing Under 37 C.F.R. §1.8(a)<br><br>I hereby certify that this correspondence and all marked attachments are being deposited on Dec. 15, 2003 with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.<br><br>By: Laura V. Largey<br>Laura V. Largey |

## DECLARATION PURSUANT TO 37 C.F.R. § 1.132

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Daniel P. Gold, declare as follows:

1) I am a co-inventor of the above-identified U.S. Patent Application Serial No. 09/927,121. I am also a co-inventor of the provisional applications to which this application claims priority: 60/279,079, 60/224,723, and 60/224,722.

2) I have been working in the field of immunology throughout my academic career and have authored over fifty abstracts and papers in the field.

3) I have been employed by Favrille, Inc. since January, 2000 when I co-founded the corporation. From the formation until July, 2003, I was the Executive Vice President of Research and Development. In July, I was promoted to the Chief Scientific Officer.



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4) As described in the above-captioned application, my co-workers and I have developed methods and compositions for treating B cell mediated pathologies. The genetic regions encoding the particular variable regions derived from a patient's B cell mediated pathology, collectively termed the idiotype or Id, are isolated from a biopsy. These gene segments are cloned into an immunoglobulin framework expression vector and expressed in insect cells. Following expression, as described in the specification, patients are treated by immunization with the Id fusion protein conjugated to KLH together with GM-CSF. As described below, following administration of FavId™ a beneficial therapeutic effect, *i.e.*, tumor shrinkage in the patient, is observed. In multiple cases complete responses were obtained.

5) To avoid long periods of cytotoxic bridging therapy while the immunogen is being prepared, idiotype-protein production must be very rapid. Our invention meets this need by being extremely rapid, resulting in a therapeutic advantage of (1) not requiring bridging therapy and (2) being able to optimize the timing following the previous therapy. Further, the speed also holds the costs down. Finally, although our invention does not require the production of large quantities of Id protein, the cloned vector for producing the Id protein can be readily stored for extended periods of time.

**A. Production of FavId™ Immunogen Is Extremely Rapid.**

6) Production of FavId™ is extremely rapid and distinguishes this technique in comparison to other technologies for the production of chimeric idiotypic proteins. Using the current protocols developed by Favrille and set forth in the specification, the total time from biopsy to having the baculovirus plasmid stored in a vial is 12 days. The analysis of a biopsy from a patient takes approximately three days for RNA extraction and cDNA cloning, three days for DNA sequencing and identification of tumor specific $V_H$ and $V_L$ genes, followed by five days to clone $V_H$ then $V_L$ into the baculovirus expression vector and sequence them, with one day required to prepare the final vector and aliquot it into vials. Following preparation of the baculovirus vector, production of the protein is extremely rapid. Overall, the cell culture operations require thirteen days: five days for the transfection, four days for the viral amplification, one day to obtain the viral titer and three days required for protein production. Following production of the protein in the viral cell culture, two days are required to purify the FavId™ protein, and final preparation, including conjugation to KLH, is two days. The typical

yield is 60 vials at 1 mg/ml of finished product each, consisting of FavId™ and KLH at a roughly 1:1 ratio.

7) Thus, from the biopsy to being ready to administer the FavId™ to a patient requires less than thirty days. Further, FavId™ is produced by the simultaneous production of both peptide chains from a single vector, rather than the more cumbersome use of co-transfecting two plasmids into a single cell with subsequent selection of dual expressing transfectants.

**B. Current Preparation of FavId™.**

8) FavId™ is a patient and tumor-specific B-cell immunoglobulin idiotype (Id) protein produced in insect cells which is complexed with KLH and administered as an idiotype immunogen to patients with follicular NHL. To prepare FavId™, tumor samples from a peripheral lymph node are biopsied. Biopsy samples are used to generate patient idiotype-specific recombinant chimeric immunoglobulin proteins as outlined herein and as described in the specification. To begin the process, single cell suspensions of patient lymph node biopsies are obtained by forcing the biopsied lymphoma tissue through a steel mesh screen.

9) Total RNA from the homogenized lymph node cells is isolated and used as template for first strand cDNA synthesis. Both heavy and light chains from the lymphoma-specific immunoglobulins are identified by PCR amplification of cDNAs encoding them using, in part, constant region specific antisense primers.

10) Parallel reactions are conducted using cDNA prepared from the patient's peripheral blood lymphocytes. A comparison of PCR products generated by pairs of primers derived from the tumor biopsy cDNA leads to the identification of the candidate tumor-specific $V_H$ and $V_\kappa$ or $V_\lambda$ subfamily over-represented in the lymphoma. For each patient, two independent analyses are performed from starting cellular fractions. PCR products from reactions determined to contain the tumor specific variable sequences for heavy and light chains are cloned directly into plasmids, and introduced into competent *E. coli* cells. Plasmids isolated from individual bacterial colonies are sequenced via high-throughput automated DNA sequencing. A V-region derived sequence could be considered tumor specific if it is present in 75% of the samples, for example, if 18 or greater of the 24 form a consensus group when analyzed using software as described in the specification.

11) After the tumor derived sequences for $V_H$ and/or $V_L$ regions are isolated as described above, oligonucleotide primers are used to amplify the patient-specific sequences bracketed by restriction enzyme sites for cloning into the expression vector below.

12) Using either pTRABacHuLC$_\kappa$HC$_{\gamma1}$ or pTRABacHuLC$_\lambda$HC$_{\gamma1}$ (construction of the vectors is described in specification), genes are inserted for a patient's $V_L$ region containing the unique cloned sequences Stu I and Dra III between the alkaline phosphatase signal sequence and the $\lambda$ or $\kappa$ constant region, and genes for any $V_H$ region containing the unique cloned sequences Spe I and Apa I between the melittin secretory signal sequence and the IgG$_{\gamma1}$ constant region. The recombinant DNA plasmids are verified by DNA sequencing and are designated pTRABac(NHL-$V_L$)LC$_\kappa$(NHL-$V_H$)HC$_{\gamma1}$ or pTRABac(NHL-$V_L$)LC$_\lambda$(NHL-$V_H$)HC$_{\gamma1}$. Vectors are assigned a reference number corresponding to a patient, *e.g.*, FV8786-001.

13) The resulting expression vector can then be transduced into *Spodoptera frugiperda* insect cells to produce recombinant budded baculovirus. The recombinant high-titer baculovirus is serially amplified in *Sf9* cells to produce a high titer recombinant baculovirus stock. This high titer recombinant baculovirus stock is then used to infect *Trichoplusia ni* cells for subsequent chimeric idiotype protein production.

14) The chimeric proteins are purified by Protein A Sepharose™ affinity columns. Other protein columns such as protein G, protein L, or other proteins that are able to bind to an immunoglobulin binding domain could be used in the same manner. The chimeric Id proteins are further purified by ion exchange chromatography and size exclusion chromatography.

15) Once purified, the idiotypic protein is conjugated to GMP grade KLH via glutaraldehyde crosslinking. Each vial of final product is labeled with the lot number, patient identifier, vial number and date vialed. Ten percent of the final vialed lot is tested for sterility and the presence of endotoxin. Multiple vials are retained for archival purposes.

16) A 1 ml aliquot of sample of infected insect cell production culture supernatant is harvested and checked by PCR DNA sequencing. Id protein purity is checked by gel filtration chromatography, SDS-PAGE and ELISA. For Id protein to be released, four criteria are checked: (1) The DNA sequence of idiotype-variable genes in baculovirus from production supernatant

must be identical to the DNA sequence in the production vector. (2) The idiotypic protein concentration must be greater than 0.5 mg/ml based on $OD_{280}$. (3) The major peak area must be greater than 90% of area in evaluated peaks on Superose™ 6 analytical chromatography. (4) The major chromatographic peak must correspond to the human IgGκ (or λ) ELISA activity peak.

17) The final vaccine product, Id-KLH, is tested for endotoxin levels by a kinetic turbidity microplate assay and must have a level below 350 endotoxin units (EU) per ml. Ten percent of the lot is tested for sterility on a 14-day test; it tests negative or is discarded.

**C. Clinical Trial of FavId™ Following Cytoreductive Therapy.**

18) Using the methods and compositions as described above and in the specification, as well as methods known to those of skill in the art, my co-workers and I have conducted two clinical trials as well as provided FavId™ for an additional clinical trial. The fast and efficient preparation of the FavId™/KLH conjugate allowed these trials to be performed. In general, the methods described in the specification are first used to generate FavId™ compositions. In the first clinical trial, the ability of FavId™ to produce tumor regressions (complete response (CR), partial response (PR), minor response (MR)) in previously treated patients with relapsed follicular NHL was evaluated. Patients were selected with stable or progressive disease requiring treatment following prior chemotherapy and/or rituximab with four or less prior chemotherapy regimens. For entry in the trial, patients were required to show bidimensionally measurable disease, ECOG performance status (PS) of 0-2 (Eastern Cooperative Oncology Group), as well as having tumor tissue accessible for biopsy.

19) A total of 66 biopsies were collected. Twenty-six of these patients were not eligible for FavId™ production because of either an incorrect diagnosis, finding no tumor cells in their biopsy, or protocol eligibility violations. FavId™ was successfully generated for all of the 40 eligible patients. To date, 32 patients have received FavId™. Of the patients treated, 20 are male, and 12 are female; their median age was 53 years (range 35-76). Prior treatment regimens included chemotherapy and rituximab (19 patients), chemotherapy alone (8 patients) or rituximab alone (5 patients). The average number of prior therapies was 2.5 (range 1 to 4) and

the mean SPD (Sum of the Products of the Diameters) at baseline was 58 $cm^2$ (range 3.2 - 231.4). Three patients had small lymphocytic lymphoma (SLL) & chronic lymphocytic leukemia (CLL).

20) Patients are treated by administration of FavId™ (1 mg) subcutaneously once a month for six months. GM-CSF (250) mcg was given at the FavId™ injection site on Days 1-4. Following the first 6 months of FavId™, patients with at least stable disease (SD) are eligible to continue receiving FavId™ every other month.

21) All 32 patients are evaluable for toxicity and 27 patients are evaluable for efficacy. In almost a third of the patients (30%), tumor regression was observed: one complete response (4%), three partial response (11%) and four minor response (15%). In addition, almost half (13) of the patients had stable disease (48%) and while only six had progressive disease (22%). Median time to progression (TTP) for all patients currently is 6.2 months with observations continuing. The patient showing complete response had stable disease after 3 doses of FavId™, a partial response after 6 doses and became a complete response at 18 months. This patient is continuing to receive FavId™. Of 3 patients attaining a partial response, one has relapsed after 26 months and 2 are continuing to receive FavId™ at 16 and 19 months respectively. Average TTP among responders (complete response + partial response) is currently 19+ months (range 15+, 16+, 19+ and 26). Three of the 4 responders tested all mounted a T-cell response to their idiotype. Negative predictors of response are: >100 $cm^2$ tumor at baseline, a diagnosis of SLL/CLL and > 2 prior therapies.

22) No serious adverse events related to the FavId™ treatment were reported during the clinical trial. Other adverse events are infrequent with injection site reaction being most common.

23) Thus, FavId™ used as a single agent in this dose and schedule is extremely well tolerated and can induce prolonged tumor regressions in previously treated patients with relapsed follicular NHL. It is possible that utilizing cytoreductive therapy prior to FavId™ and enrolling less heavily pre-treated patients may enhance the benefits of the therapy.

**D. Clinical Trial of FavId™ Foll wing Autologous Stem Cell Transplantation.**

24) Using the methods and compositions as described in the above-identified application, as well as methods known to those of skill in the art, I, along with my co-workers, have provided FavId™ for a clinical trial conducted at UCSD using FavId™ following autologous stem cell transplantation (ASCT). The methods described above and in the specification of the above-identified application are used to generate FavId™ compositions.

25) It was shown previously that immunization with an Id protein can provide protection from a tumor challenge and also shrink established tumors in a murine model. Human studies have also demonstrated efficacy with long-term remissions reported. Molecular responses have been induced in patients with minimal residual disease following chemotherapy. As measured by the development of idiotype-specific humoral or cellular immunity, responses occurred in approximately 50% of patients. A higher response rate occurs in patients with minimal disease at the time of immunization.

26) Autologous stem cell transplant is a treatment option in patients with both mantle cell lymphoma (MCL) and follicular lymphoma (IL). Unfortunately, relapse is inevitable even following this treatment. Attempts to reduce or delay relapse include purging and the post-transplant use of monoclonal antibodies. Id immunization should be efficacious in the post-ASCT setting.

27) In order to evaluate the feasibility and efficacy (using the development of an immune response as a surrogate endpoint) of Id immunization following ASCT, we are conducting a non-randomized phase 2 study. The results for the initial 6 patients are presented here. Six patients (four with MCL; 2 with IL) underwent a lymph node biopsy to allow for immunogen preparation. Following identification of the Id heavy and light chain genes, their DNA was cloned into an expression system as described in the specification. The resulting Id protein was conjugated to keyhole limpet hemocyanin (KLH). Starting at a median of 5 months (range 3-6.1 months) post-ASCT (high dose regimen = BEAM (bis-chloro-nitroso-urea / carmustine, etoposide, cytarabine and melphalan), patients received 5 monthly immunizations with the conjugate plus locally administered GM-CSF. Prior to transplantation, all MCL patients received the hyper-CVAD (cyclophosphamide, vincristine, doxorubicin, dexamethasone) regimen with or without rituximab. Three of these patients had a complete response or a

complete response/unconfirmed and one had a partial response at the time of transplantation. Of the IL patients, one had a partial response and one had stable disease. Immunization was well tolerated with no grade 3 or 4 toxicities attributable to immunization. Serum anti-KLH and anti-Id antibody titers are evaluated by ELISA as a measure of humoral responsiveness. Anti-CD4+ T cell responses directed at Id and KLH are assessed as a measure of cellular responsiveness. Cellular and humoral immune responsiveness is shown below.

| **Immune Responses to Idiotype immunization Post-ASCT** | | | | | |
|---|---|---|---|---|---|
| | | Humoral | Humoral | Cellular | Cellular |
| Patient | Histology | Anti-KLH | Anti-Id | Anti-KLH | Anti-Id |
| 1 | IL | After 2nd Iz | After 2nd Iz | After 1st Iz | After 1st Iz |
| 2 | IL | After 2nd Iz | NSR | After 1st Iz | After 5th Iz |
| 3 | MCL | After 4th Iz | After 4th Iz | After 1st Iz | After 1st Iz |
| 4 | MCL | NR | NR | NT | NT |
| 5 | MCL | After 3rd Iz | NSR | After 1st Iz | After 3rd Iz |
| 6 | MCL | After 2nd Iz | After 2nd Iz | After 2nd Iz | After 2nd Iz |

Iz=Immunization; IL=indolent NHL; MCL=mantle cell lymphoma; NSR=non-specific response; NT=not tested; NR=no response; P=results pending (to be presented in December)

28) Both IL patients are in complete response at 9 and 20 months post-ASCT. Three of the MCL patients (nos. 3, 5 and 6) are in complete response at 22, 15 and 10 months respectively post-ASCT. A fourth MCL patient (Patient 4 in table) had progressive disease at 12 months post-ASCT.

29) As observed in this clinical trial, MCL and IL patients develop early and robust immune responses post-chemotherapy and ASCT. This may well translate into longer post-transplant disease-free survival.

**E. Clinical Trial of FavId™ Coupled to Rituximab Treatment.**

30) This study was designed to evaluate the ability of FavId™ to increase or prolong the objective response rate following rituximab compared to historical data for rituximab alone and evaluates the ability of patients treated with FavId™ following rituximab to mount an immune response to KLH and idiotype. The fast and efficient preparation of the Id/KLH conjugate allowed these trials to be performed.

31) Eligible patients with grade 1 or 2 follicular NHL who are treatment naive; relapsed or refractory following chemotherapy or relapsed following a response (complete response or partial response) to prior rituximab therapy; two prior chemotherapy regimens, bidimensionally measurable disease, ECOG performance status (PS) of 0-2 and tumor tissue accessible for biopsy.

32) Treatment: Rituximab 375 mg/m$^2$ is given weekly for 4 weeks. Subsequent to the last dose of rituximab, FavId™ (1 mg) is administered subcutaneously once a month for six months. GM-CSF (250 mcg) is given at the FavId™ injection site on Days 1-4. Patients with at least stable disease after six doses of FavId™ may continue receiving the vaccine every other month for six doses and then every three months until disease progression. Eighty-three patients have been biopsied and 72 were eligible to enroll. The eligible patients were 39 males and 33 females with a median age of 52 yrs (range 32-85). Nineteen patients were treatment naive and the remaining 53 patients had prior therapy with: chemotherapy and rituximab (27 patients), chemotherapy alone (21 patients) or rituximab alone (5 patients). FavId™ has been generated in 100% of eligible patients to date. All 72 patients have begun rituximab. Twenty-nine patients have begun FavId™.

33) To date, 21 patients are evaluable. The response rate to rituximab alone is 29% (zero complete response; six partial responses) assessed at three months post the start of rituximab. Additionally, six patients (29%) had a minor response, eight (37%) had stable disease and one (5%) had progressive disease. After three doses of FavId™, five patients with a partial response following rituximab continue as partial response and all five of these patients have had continued tumor shrinkage. In addition, two patients with a minor response converted to a

partial response resulting in an overall response rate of 38%. Six patients have now completed six doses of FavId™. Of these, only one has progressed.

34) Immune data: No patient who has completed all six courses of FavId™ has made immunization-induced antibodies against KLH as yet. Early studies on cell mediated responses to KLH and autologous Id using flow cytometry to measure cytoplasmic cytokine levels suggest that patients do however make strong CD4+ T responses to both components of the immunogen preparation.

35) Four serious adverse events were reported, but none were considered related to FavId™. Other adverse events were infrequent with injection site reaction being most common.

36) Conclusion: FavId™ administered in this dose and schedule following rituximab is extremely well tolerated and may increase the response rate and extend the time to progression following rituximab.

**F. Conclusion.**

37) Use of FavIdTM as described herein and in the specification produces a beneficial therapeutic effect in patients. Tumor shrinkage is observed in multiple patients following administration of FavId™. In multiple cases complete responses were obtained. Further, utilization of our invention is extreme rapidly, an additional therapeutic advantage.

38) I declare under penalty of perjury that the foregoing statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code §1001, and that such willful false statements may jeopardize the validity of the patent. Executed this 10th day of December, 2003.

Date: 12. 10., 2003

Daniel P. Gold

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| In re the Patent Application of: | Group Art Unit: 1644 |
| Applicant: GOLD, et al. | Examiner: Jessica H. Roark |
| Serial No.: 09/927,121 | |
| Filed: August 10, 2001 | |
| Title: METHOD AND COMPOSITION FOR ALTERING A B CELL MEDIATED PATHOLOGY | |

## DECLARATION PURSUANT TO 37 C.F.R. § 1.132

Hon. Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

I, Jonathan W. Uhr, declare as follows:

1) I am a professor at The University of Texas Southwestern Medical Center at Dallas where I hold the Raymond and Ellen Willie Distinguished Chair in Cancer Research. I received my Bachelor of Arts from Cornell and my Doctorate in Medicine from New York University. I am a member of the National Academy of Sciences. Further details of my academic career and background are set forth in my Curriculum Vitae, attached as Exhibit 1.

2) I have been working in the field of immunology throughout my academic career, served as the President of the American Association of Immunologists, and have authored almost 400 papers in the field. My current research concerns immunologic approaches to the diagnosis and therapy of cancer.

3) I have reviewed U.S. Patent Application Serial No. 09/927,121 by Gold and Shopes. I have reviewed the office action from the United States Patent and Trademark Office

dated August 12, 2003. I have also reviewed the referenced publications of Edelman, Denney Jr., Mroczowski and Tan, which are discussed below.

4) The Gold Application describes a technique to rapidly isolate the genetic region encoding a patient's Id protein from the patients' malignancy, express the Id protein in insect cells, and use the expressed Id protein to stimulate an immune response in the same patient.

5) The process is carried out in the following manner: cancerous cells from a patient are isolated via biopsy. The DNA sequences encoding the variable regions of expressed antibody genes are cloned and compared to select the variable region genes (idiotype) associated with the lymphoma. The idiotype (Id) is cloned into a vector containing the constant regions of immunoglobulin molecules, either the κ or λ chain, and currently, the $IgG_{\gamma 1}$ heavy chain. The chimeric Id protein is expressed in insect cells, isolated, conjugated to KLH, and administered to the same patient that furnished the idiotypic sequences and thereby stimulates an immune response.

6) I have reviewed U.S. Patent No. 5,972,334 (Denney Jr.) which was cited by the patent examiner. Denney Jr. treats lymphoma patients by isolating lymphoma cells and producing idiotypic proteins in mammalian cells.

7) I have reviewed Edelman US Patent No. 6,312,690 B2. Edelman describes the production of an antibody with known specificity in insect cells.

8) I have reviewed Examiner Roarke's rejection of claims 1, 3, 10-14, 18, 23-33 under 35 U.S.C. § 103 over the Denney Jr., Edelman, Mroczkowski and Tan references. I do not agree with the Examiner's conclusions that at the time of the filing of the Gold Application, one of skill in the art would have been motivated to combine the treatment method set forth in Denney Jr. with production of an antibody of known specificity in insect cells to produce the invention set forth in the Gold application.

9) One skilled in the art seeking to produce the Id proteins to immunize patients would not select the insect cell production system of a monoclonal antibody set forth in Edelman. Edelman describes a method for producing a large amount of a single well-characterized antibody for use as a passive immunotherapeutic. Edelman began with a pre-tested monoclonal antibody and wanted to make large quantities of that particular antibody. The binding specificity of the antibody was well characterized and Edelman's purpose was to make antibody that had that same binding specificity. Edelman could directly test the binding of the

antibodies produced in the insect cells to determine their binding characteristics and verify their functionality prior to use.

10) The process described in the Gold Application is intended to induce an immune response in a patient, and does not use an antibody having a known binding specificity. Proteins produced in insect cells are glycosylated, but they are not glycosylated in the same manner as proteins produced in mammalian cells. Some of the differences in glycosylation in insect cells are described in Altman, F., et al., Glycoconjugate J. 16:109-123 (1999). In the Denney Jr. patent cited by the patent examiner, the idiotypic proteins are produced in mammalian cells and will be glycosylated in a mammalian fashion. One skilled in the art could not predict the response of a patient's immune system if the insect-produced Id protein was administered as an immunogen because of the insect cell glycosylation. The difference in the glycosylation of the Id protein could cause the patient's immune system to respond in a different manner than if the Id protein was produced in mammalian cells. In fact, the immune response to the patient's Id protein having the insect cell glycosylation may not occur at all, possibly causing the immunization process against the tumor to fail.

11) Given the unpredictability of immunizing with an Id protein having insect cell glycosylation, one of skill in the art at the time of filing the Gold Application would not have selected insect cell as a means of producing the required idiotypic proteins. Any potential advantages Edelman may teach would be offset by the uncertainties of using a protein production system that is not as well characterized as, for example, CHO cells. The uncertainty would be exacerbated by the wide variety of patient-specific Id protein sequences to be synthesized in order to provide patient-specific treatment.

12) A recent survey of biotechnological products published in Nature Biotechnology reveals that the vast majority of therapeutic products are produced in E. coli or CHO cells: "[t]o date, virtually all recombinant proteins approved for human use are produced in either engineered *Escherichia coli* and *Saccharomyces cerevisiae*, or in animal cell lines (Chinese hamster ovary or baby hamster kidney)." Gary Walsh, Biopharmaceutical benchmarks – 2003, 21 Nature Biotechnology 865, 869 (2003). Because of the lack of experience with insect cell production systems, there would be heightened review from regulatory agencies confronted with a novel (with regard to the production of therapeutics) protein synthesis system.

13) Further evidence that insect cell glycosylation significantly alters the properties of proteins produced in those cells is provided by a recent review of the possibility of production of therapeutics in insect cells focused on the differences in glycosylation by Altmann, F., et al., "Insect Cells as Hosts for the Expression of Recombinant Glycoproteins," Glycoconjugate J. 16:109-123 (1999). The authors point out the potential in insect-produced recombinant proteins of α1,3-fucosylation producing highly immunogenic glycosylation. Even in the absence of that, the authors state in the abstract that "the truncated N-glycans of glycoproteins produced in insect cells constitute a barrier to their use as therapeutics." The authors further point out that glycosylation is generally expected to have a significant effect on a protein's antigenicity (pg. 112). All this further argues against selecting insect cells as a means of producing the required idiotypic proteins at the time of filing the Gold Application.

14) I declare under penalty of perjury that the foregoing statements made herein of my knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Title 18, United States Code §1001, and that such willful false statements may jeopardize the validity of the patent. Executed this 15 day of Dec, 2003.

Date: Dec 15, 2003

Jonathan W. Uhr

Jonathan W. Uhr, M.D.

# CURRICULUM VITAE

Daniel P. Gold, Ph.D.

<u>Current Status</u>:


| | |
|---|---|
| Name: | Daniel P. Gold, Ph.D. |
| Business Address: | Favrille, Inc.<br>10865 Altman Row<br>San Diego, CA 92121 |
| Business Phone: | (858) 526-8012 |
| Email: | dgold@favrille.com |


<u>Personal Statistics</u>:

| | |
|---|---|
| Date of Birth: | July 28, 1954 |
| Place of Birth: | San Francisco, California |
| Marital Status: | Married |

<u>Education</u>:

University of California, Los Angeles - BA (Biology), 1976.
Tufts University School of Medicine - Ph.D. (Immunology), 1983.
Laboratory Head: Dr. Henry Wortis

<u>Professional Record</u>:

Fellow, Center for Cancer Research, Massachusetts Institute of Technology, Cambridge, Massachusetts (Molecular Immunology), 1983-1984. Laboratory Head: Dr. Susumu Tonegawa.

Fellow, Dana Farber Cancer Center, Boston, Massachusetts ( Molecular Immunology ), 1984-1986. Laboratory Head: Dr. Cox Terhorst.

Assistant Member, Division of Immunology, Medical Biology Institute, La Jolla, California, 1986-1990.

Assistant Member, La Jolla Institute for Experimental Medicine, La Jolla, California, 1990-1991

Associate Professor, Sidney Kimmel Cancer Center, San Diego, California, 1991- 2003

Founder, Executive Vice President Favrille, Inc. Jan. 2000 – July 2003

Chief Scientific Officer, Favrille, Inc. July 2003-present

Awards and Honors: Cancer Research Institute Fellow, 1985-1987.
Basil O'Connor Scholar of the March of Dimes, 1987.
Junior Faculty Awardee, American Diabetes Association, 1990.
Distinguished Scholar Award, Immune Response Corporation, 1992-1994
Leukemia Society of America Scholar, 1994-1999

Society Memberships: Member, American Association of Immunologists, 1988-present
Member, American Society of Hematologists, 2000-present
Member, International Society for Biologic Therapy, 2000-present
Member of the Board, Leukemia and Lymphoma Society San Diego Chapter, 1998-prese

Advisory Activities: Associate Editor, Journal of Immunology, 1993-1999
Member Editorial Review Board, Cancer Gene Therapy, 1995-present
Ad Hoc Reviewer, Journal of Clinical Investigation, 1994-present
Review Panel, Oral Tolerance, NIH-NIAID, 1993
Review Panel, Research Personnel, American Cancer Society, 1994
Review Panel, MAMDSC, NIAMS, 1995
Ad Hoc Reviewer, Veteran's Administration Merit Awards, 1995-present
Member and Co-Chair Immunology Panel, International Juvenile Diabetes Foundation Review Board, 1997-prsent
Review Panel, Centers of Excellence in AI, NIH-NIAID, 1999
Review Panel, New Therapies for Type I Diabetes, NIH-NIAID, 1999
Member, IMS Study Section, NIH-NIAID, 1999-present

Teaching: Lecturer on Autoimmune Disease in AAI Advanced Course in Immunology, 1995 & 1996

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**REVIEWS:**

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# CURRICULUM VITAE

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### ACADEMIC RECORD:

Rutgers Preparatory School, June, 1944
Cornell University, A.B., 1948
New York University School of Medicine, M.D., 1952
American Board of Internal Medicine, 1960

### PROFESSIONAL EXPERIENCE:

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| 1964 - 1974 | Consultant in Internal Medicine, Manhattan Veteran's Hospital |
| 1963 - 1972 | Associate Attending Physician, University Hospital |
| 1959 - 1972 | Associate Visiting Physician, Bellevue Hospital |
| 1956 - 1957 | Chief Resident in Medicine, The Mount Sinai Hospital |
| 1954 - 1955 | Assistant Resident in Medicine, The Mount Sinai Hospital |
| 1953 - 1954 | Resident in Pathology, The Mount Sinai Hospital |
| 1952 - 1953 | Intern, The Mount Sinai Hospital |

### ACADEMIC EXPERIENCE:

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| 1997 - Present | Member, Cancer Immunobiology Center, University of Texas Southwestern Medical School |
| 1990 - Present | Raymond and Ellen Willie Distinguished Chair in Cancer Research |

## ACADEMIC EXPERIENCE (Continued):

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| 1988 – Present | Professor, Cancer Immunobiology Center |
| 1972 - Present | Professor of Microbiology and Internal Medicine, University of Texas Southwestern Medical School |
| 1972 - 1997 | Chairman, Department of Microbiology, Professor of Internal Medicine, University of Texas Southwestern Medical School |
| 1982 - 1991 | Mary Nell and Ralph Rogers Professor of Immunology, University of Texas Southwestern Medical School |
| 1970 - 1971 | Visiting Professor, Department of Microbiology, Yale University |
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| 1962 - 1972 | Director, Irvington House Institute for Rheumatic Fever and Allied Diseases, New York University School of Medicine |
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| 1962 | USPHS Career Development Award (2 months) |
| 1961 - 1962 | Commonwealth Fellow, Walter and Eliza Hall Institute of Medical Research (Sir F. MacFarlane Burnet) |
| 1958 - 1962 | Assistant Professor of Medicine, New York University School of Medicine |
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## EDITORIAL BOARDS, CONFERENCES, AND COMMITTEES:

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| 1993 - 1997 | Member, Medical Advisory Board, Howard Hughes Medical Institute |
| 1984 - | Associate Editor, *Advances in Immunology* |
| 1984 | Head, U.S.-Japan Panel of the Cooperative Science Program in Immunology |
| 1983 - 1987 | Member, Scripps Clinic Scientific Review Board |
| 1983 - 1984 | President, American Association of Immunologists |
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| 1980 - 1986 | U.S. Representative, International Union of Immunological Societies |
| 1980 - 1989 | Member, Scientific Review Board, Howard Hughes Medical Institute |
| 1978 - 1985 | Councilor, American Association of Immunologists |
| 1976 - | Editorial Board, *Immunological Reviews* |
| 1974 - 1980 | Advisory Editor, *Immunogenetics* |
| 1973 - 1978 | Editorial Board, *Clinical Immunology and Immunopathology* |
| 1971 | Program Chairman, First International Congress of Immunology |
| 1970 - | Editorial Board, *Cellular Immunology* |
| 1969 - 1973 | Deputy Director, Commission on Immunization, Armed Forces Epidemiological Board |

## EDITORIAL BOARDS, CONFERENCES, AND COMMITTEES (Continued):

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| 1969 - 1973 | Member, Allergy and Immunology Study Section, USPHS |
| 1969 - 1984 | Advisory Editor, *Journal of Experimental Medicine* |
| 1966 - 1968 | Member, Panel on Regulatory Biology, National Science Foundation |
| 1965 - 1973 | Associate Editor, *Journal of Immunology* |
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## PROFESSIONAL SOCIETIES:

American Association of Immunologists
American Association of Pathologists
American Society for Clinical Investigation
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Scandinavian Society of Immunology (Honorary Member)
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## AWARDS:

Phi Beta Kappa
Alpha Omega Alpha
Phi Delta Epsilon Scholarship Prize, New York University School of Medicine
Arnold Prize in Surgery, New York University School of Medicine
Newcomb Cleveland Prize of the American Association for the Advancement of Science, 1963
Squibb Award, Infectious Diseases Society of America, 1971
New York University Alumni Award for Achievement in the Basic Sciences, 1978
Medal of the Faculty of the Medical School of Montpellier, France, 1984
President, AAI, 1984
National Academy of Science, 1984
Fellow of the American Association for the Advancement of Science, 1990
The Gibson D. Lewis Award for Cancer Control (Research Achievement), Texas Cancer Council, 1991
American Academy of Arts and Sciences, 1993
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## MILITARY SERVICE:

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## BIBLIOGRAPHY


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